



Fertility & Surgical Associates of California

0465 '99 DEC 28 AM 1:05

December 17, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket #: 97N2-48S, suitability determination for donors of human cellular and tissue based products

To Whom It May Concern:

I am extremely concerned regarding the proposed regulations for donor egg/IVF cycles. Specifically, quarantining embryos for six months prior to transfer is medically unnecessary, impractical and would deny thousands of women the ability to have a child. There is no evidence of recipient HIV susceptibility nor has there ever been a case of a woman contracting HIV or HIV-related illness from a donor egg cycle when the donor has been properly screened and found to be negative for the appropriate sexually transmitted diseases. Quarantining embryos would cause undo physical and mental hardship for these couples who are desperately desirous for having a child. In addition, the medical costs associated with donor IVF would skyrocket as the pregnancy rates with frozen IVF cycles are approximately half of what one would obtain using fresh embryos. Finally, thousands of embryos would be lost from the proposed freezing and subsequent thaw.

I am optimistic that the committee will review the data carefully and reach a rational conclusion following consultation with the American Society for Reproductive Medicine and physicians involved in the care of these couples.

Sincerely,

Gary D. Hubert, M.D.

GDH:jv

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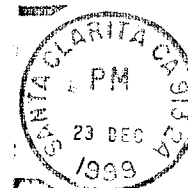
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